### REMARKS

# **Summary of the Amendments**

By the foregoing amendment, claims 31, 33, 36 and 37 are amended, claims 35 and 38 are canceled, and claims 48-50 are added, whereby claims 1-34, 36, 37, and 39-50 remain pending. Claims 1-30 and 39-47 are withdrawn from consideration as being drawn to a non-elected invention. Of the pending elected claims, claim 31 is independent.

Support for the amendments to the claims can be found, for example, explicitly or implicitly in Applicants' originally filed specification and claims. Support for the amendment to claim 31 can be found, for example, in originally filed claims 35 and 38. Support for the amendment to claim 33 can be found, for example, at page 13, in the third full paragraph. Support for the amendment to claims 36 and 37 can be found, for example, in original claim 35. Support for new claim 48 can be found, for example, in the first full paragraph on page 37. Support for new claim 49 can be found, for example, in the fourth full paragraph on page 7. Support for new claim 50 can be found throughout the specification, and for example, in the first full paragraph on page 16. Applicants submit that no new matter is added.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

## **Information Disclosure Statement**

Applicants thank the Examiner for consideration of the Information Disclosure Statements filed August 4, 2004, September 28, 2004 and September 29, 2005, by returning initialed copies of the Forms PTO-1449 submitted therein.

### **Restriction Requirement**

Applicants note that the Restriction Requirement in the paper of September 27, 2006 has been made final. Applicants are permitting claims 1-30 and 39-47 to remain pending subject to possible reconsideration of the requirement until such time as an indication of Allowability is received, with possible rejoinder of the non-elected subject matter.

## **Claim of Foreign Priority**

Applicants thank the Examiner for the acknowledgement of Applicants' claim of priority. Applicants note that the Examiner has not confirmed receipt of the certified copy of the Japanese priority application. Therefore, the Examiner is requested to confirm receipt of the Japanese priority application, which was submitted when the application was filed April 12, 2004 with the next communication from the Patent and Trademark Office.

#### **RESPONSE TO REJECTIONS**

## 1. Response to Rejection under 35 U.S.C. § 112, second paragraph

The Office Action rejects claims 31, 32, and 35-37 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Office Action submits that the phrases "allowed to adhere" (claims 31 and 32), "wherein the coating layer is **mainly** made of calcium

phosphate-based compound" (claim 35), and "**fine** particles" (claim 36 and 37) are indefinite. (See, Office Action, pp. 3-5, emphasis in original).

In response, and without expressing any agreement or acquiescence with the rejections of record, Applicants have amended claims 31, 33, 36 and 37 to either remove or replace the terms rejected in the Office Action.

Regarding the term "mainly" in claim 35, Applicants note that this term is presently included in claim 31. Applicants further submit that one having ordinary skill in the art would readily understand the meaning of this term as comprising more than 50%, as noted by the Examiner, whereby this ground of rejection is without appropriate basis and should be withdrawn.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection of claims 31, 32, and 35-37.

# 2. Response to Rejections under 35 U.S.C. § 102

The Office Action contains the following rejections under 35 U.S.C. § 102:

- (a) Claims 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) as being anticipated by NILSSON (GB 2,093,040A, published as WO 82/00660).
- (b) Claims 31, 32-34, and 38 are rejected under 35 U.S.C. § 102(b) as being anticipated by HENDERSON (U.S. Pat. No. 4,448,884).
- (c) Claims 31, 32-34, and 38 are rejected under 35 U.S.C. § 102(b) as being anticipated by MATTHEW (PhD. Thesis).

In response to the anticipation rejections, Applicants note that a rejection under 35 U.S.C. § 102 can only be maintained if **every** element of the rejected claims is found in a single prior art document, and this requirement is not met.

Applicants respectfully submit that the cited documents of NILSSON, HENDERSON, and MATTHEW fail to disclose at least a coating layer containing a calcium phosphate-based compound as a main component thereof, as recited in dependent claim 35 (now canceled), and presently recited in independent claim 31.

Moreover, Applicants respectfully submit that the cited document of NILSSON fails to disclose at least "a magnetic particle ... formed by compounding a resin material and a magnetic material..." as recited in dependent claim 38 (now canceled), and presently recited in independent claim 31.

Thus, in view of the foregoing, Applicants respectfully submit that the rejections under 35 U.S.C. § 102 should be withdrawn because the cited documents fail to disclose **every** element of the rejected claims.

## 3. Response to Rejection under 35 U.S.C. § 103(a)

The Office Action rejects claims 31-38 under 35 U.S.C. § 103(a) as being unpatentable over STARLING (U.S. Pat. No. 6,210,715) or KITANO (U.S. Pat. No. 5,540,995), and further in view of NILSSON (GB 2,093,040A, published as WO 82/00660).

The Office Action submits that STARLING discloses, among other things, cell culture carriers to which cells are allowed to adhere to and grow on surfaces thereof, wherein each of the carriers comprising glass or polymeric beads, but does not explicitly teach cell culture carrier comprising a magnetic particle in combination with a polymeric resin material. (See, Office Action, p. 10-11). The Office Action submits that KITANO discloses, among other things, granular polymer composites comprising polymer beads having coated on the surface thereof a

calcium phosphate-based compound, but does not explicitly disclose a magnetic particle in combination with a polymeric resin material. (See, Office Action, p. 11).

The Office Action submits that NILSSON discloses, among other things, cell culture carriers comprising a magnetic particle having a surface, and a coating layer of gelatin or chitosan polymers. (See, Office Action, pp. 11-12).

In view of the teachings of the cited documents, the rejection asserts that it would have been obvious to incorporate the magnetic particles of NILSSON into the polymeric microbeads or cell culture composition of STARLING or KITANO, "such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof" (Office Action, p. 12).

Applicants respectfully request withdrawal of the obviousness rejection for at least the following.

Applicants respectfully submit that a *prima facie* case of obviousness is not established by STARLING or KITANO, and further in view of NILSSON for at least the following reasons. A *prima facie* case of obviousness requires:

- a) the presence of all claimed elements,
- b) the motivation to combine the separate reference teachings, and
- c) a reasonable expectation of success.

The Office Action fails to establish any of these requirements.

First, regarding the presence of all claimed elements, Applicants respectfully submit that the requirement that all claimed elements be taught or suggested in the cited documents has not been met.

For instance, the cited documents fail to disclose or suggest at least at least "a magnetic particle ... formed by compounding a resin material and a magnetic material..." as recited in dependent claim 38 (now canceled), and presently recited in independent claim 31. Therefore, the requirement that all claimed elements be taught or suggested in the cited documents has not been met, and a *prima facie* case of obviousness has not been established.

Expanding upon the above, Applicants refer the Examiner, for example, to Applicants' originally filed specification, at page 5, last paragraph, wherein it is disclosed that:

Further, in this embodiment, it is preferred that each of the magnetic particles is formed by compounding a resin material and a magnetic material. According to this method, it is possible to adjust a density (specific gravity) of the magnetic particle (consequently, the cell culture carrier) by setting compounding ratio (mixing ratio) between the resin material and the magnetic material appropriately. Further, the shape and size of the cell culture carrier can also be adjusted easily.

Still further, reference is made to Applicants' originally filed specification beginning at page 36, penultimate for further description of the preferred magnetic particle being formed of a composite material which is obtained by compounding a resin material and a magnetic material.

Accordingly, for at least this reason, the 35 U.S.C. § 103 rejection of claims 31-38 over STARLING or KITANO, and further in view of NILSSON should be withdrawn.

Applicants further submit that the Office Action fails to provide any sufficient arguments to combine, including why the documents should be combined, to arrive at the presently claimed subject matter.

For example, both of the primary documents of STARLING and KITANO, as admitted in the Office Action, fail to disclose a cell culture carrier comprising a magnetic particle. (See, Office Action, page 11, second paragraph). Moreover, while the Office Action submits that the secondary document of NILSSON discloses magnetic particles, there is no reason to arrive at

Applicants' recited subject matter following any combination of the document utilized in the rejection.

Thus, Applicants respectfully submit that the motivation set forth in the Office Action, *i.e.*, "such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof" (Office Action, p. 12), is insufficient motivation to establish a *prima facie* case of obviousness.

In any event, even if for the sake of argument, the disclosure were combined, Applicants' claimed subject matter would not be at hand because no combination of these documents would arrive at Cell culture carriers to which cells can adhere to and grow on surfaces thereof, wherein each of the carriers comprising a magnetic particle having a base body having a surface, the base body being formed by compounding a resin material and a magnetic material so that the magnetic material is dispersed in the resin material; and a coating layer containing a calcium phosphate-based compound as a main component thereof, the coating layer being provided to cover at least a part of the surface of the base body of the magnetic particle so that the cells can adhere thereto, as recited in independent claim 31.

Moreover, Applicants respectfully submit that in order to support the conclusion that the claimed invention is either anticipated or rendered obvious over the cited documents, the cited documents must either expressly or inherently teach the claimed invention or the Examiner must present a convincing line of reasoning why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Ex parte Clapp, 227 U.S.P.Q. 972 (B.O.A. 1985).

Still further, the dependent claims are patentable for at least the reasons set forth above, and for the additional features recited therein.

Accordingly, for at least the foregoing reasons, the 35 U.S.C. § 103 rejection of claims 31-38 over STARLING or KITANO in view of NILSSON should be withdrawn.

## 4. Response to Obviousness-Type Double Patenting Rejection

The Office Action provisionally rejects claims 31-38 on the grounds of obviousness-type double patenting as being unpatentable over claims 1-11 of copending application No. 11/190,868 ("ISHIKAWA")

To ensure that the record is complete, Applicants note that Application No. 11/190,868 published as U.S. Pat. App. Pub. No. 2006/0024823. A Form PTO-1449 is submitted so that the Examiner's consideration of this document can appear on the face of the issued patent. Because the form is only updating information already of record, a fee should not be necessary for its consideration. However, if any fee is required, authorization is hereby provided to charge any required fee to Deposit Account No. 19-0089.

Applicants respectfully request withdrawal of the obviousness-type double patenting rejection of claims 31-38 in view of the following remarks.

Applicants respectfully submit that the Office Action does not set forth a sufficient basis for asserting that the claims of the instant application are obvious over the claims of ISHIKAWA. For example, the rejection merely asserts that the claims are co-extensive, but does not indicate the differences between the claims, nor does the rejection include what is considered to be an obvious difference.

Application No. 10/822,006

Attorney Docket No. P24816

Moreover, Applicants note that because the rejection is provisional, the present

application can be past to issue, with a double patenting rejection, if deemed appropriate by the

Examiner, being made in the other application.

The Examiner is requested to contact the undersigned if the only item preventing the

allowance of the claims is the filing of a Terminal Disclaimer to overcome the obviousness-type

double patenting rejection over Application No. 11/190,868.

Therefore, in view of the foregoing, Applicants respectfully request withdrawal of the

obviousness-type double patenting rejection of claim 31-38.

**CONCLUSION** 

In view of the foregoing, the Examiner is respectfully requested to reconsider and

withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully requests that an early indication of allowance of the

application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is

invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted, Akira YAMAMOTO et al.

Bruce H. Bernstein Reg. No. 29,027

Wesley A. Nicolas Reg. #56.129

May 8, 2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191